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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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[Signature]
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EXAMINER

MILLER, M

ART UNIT	PAPER NUMBER
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1051

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DATE MAILED: 12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/478,299

Applicant(s)
Schenk

Examiner
Michael Meller

Group Art Unit
1651



☒ Responsive to communication(s) filed on Nov 1, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-37 is/are pending in the applicat

Of the above, claim(s) 27-34, 36, and 37 is/are withdrawn from consideration

☐ Claim(s) is/are allowed.

☒ Claim(s) 1-26 and 35 is/are rejected.

☐ Claim(s) is/are objected to.

☐ Claims are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of the election of species requirement in Paper No. 7 is acknowledged. It is noted on the record that the applicant did not traverse the restriction requirement but did elect Group I, claims 1-26 and 35 in paper number 4. The traversal of the election of species is on the ground(s) that ten independent and distinct nucleotide sequences have been determined to be a "reasonable number" of sequences to be claimed and examined in a single application without restriction and that searching for more than one cryoprotectant and more than one additional component would not be unduly burdensome to the examiner. This is not found persuasive because of the extensive literature search that is involved in the searching of such components. Applicant is reminded that while the literature search is extensive it is not co-extensive.

Thus, claims 27-34, 36 and 37 remain withdrawn from further consideration by the examiner and the species that applicants have elected reads on the cryoprotectant glycerol and a component that maintains osmolality and buffers pH. It is noted that applicant has also elected from claim 15, but the election of species was directed only to an additional component from claim 12.

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The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-26 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 35, step c), which calls for "isolating sperm from said selected sperm sample to produce isolated sperm", is confusing since a sperm sample is isolated once it is no longer in the testicles. Step c, is thus redundant in its recitation of "isolating sperm" since the sperm is already isolated.

Further, the claim is confusing since the term, "final extender" is confusing. What is the final extender final to ? There is no beginning extender.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-26 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salisbury et al. taken with Spaulding.

The claims are drawn to a method for the cryopreservation of sperm as in claims 1 and 35 using as an extender the elected extender containing glycerol and a component that maintains osmolality and buffers pH.

Salisbury teaches cryopreservation of bull semen using different extenders including glycerol (page 497) and a component that maintains osmolality and buffers pH such as sodium citrate, Tris, milk, etc. Salisbury also teaches obtaining the sperm sample cooling it to 5°C for 140 minutes (see page 475-see also pages 463-464 for additional cooling semen), adding the extender (see page 456, 499), and freezing the suspension of sperm (see pages 471, 494, 495, 503-504). The pH of the extender is 6.5 to 7.0 (page 502 and page 456). See entire reference especially the pages mentioned.

Salisbury does not teach to specifically isolate the sperm using centrifugation and does not teach using flow cytometry to select the sperm sample.

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Spaulding teaches to sort sperm for their X or Y characteristic, by flow cytometry and to centrifuge sperm cells to remove seminal plasma proteins, i.e. isolate the sperm, after cooling, see example I.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use flow cytometry to select sperm for a particular characteristic in the method of Salisbury since Spaulding teaches using flow cytometry to sort X from Y sperm. To centrifuge (isolate) the sperm sample of Salisbury after cooling would have been obvious since Spaulding teaches to remove seminal plasma proteins, i.e. isolate the sperm, after cooling.

Since Salisbury uses bull sperm it also would have been obvious to use other mammalian sperm such as equine and porcine since they are also mammalian sperm and would be expected to work well in the process of Salisbury as well. To use different mammalian sperm is well within the purview of the skilled artisan.

A 50% to 90% recovery of sperm from the centrifugation is obvious since one would want to yield as much of the sperm as possible.

The concentration of sperm in said suspension prior to freezing would be inherent to the suspension of sperm.

The order of the steps of the process of Salisbury might be out of order from the claimed process, but this still is obvious. MPEP 2144.04 IV (C) states that it is *prima facie* obvious to perform in any order steps of a process.

Thus, the claimed subject matter is obvious over the cited references.

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Any inquiries concerning this communication should be directed to Examiner Mike Meller at telephone number (703) 308-4230. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743. The Fax phone number for the art unit is (703) 308- 0294. Any inquiries of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651